

CONSUMER ALERT



Office of the Attorney General Robert E. Cooper, Jr.

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PHARMACEUTICAL COMPANY CEPHALON TO PAY \$425 MILLION FOR OFF-LABEL DRUG MARKETING

Attorney General Bob Cooper today announced that the National Association of Medicaid Fraud Control Units joined the federal government to reach an agreement with pharmaceutical manufacturer Cephalon, Inc. to settle allegations of improper off-label drug marketing.

Cephalon has agreed to pay the states and the federal government \$425 million in damages and penalties for Medicaid and other federal health care programs. Tennessee's share is estimated at \$7,653,028. In addition, the Eastern District of Pennsylvania U.S. Attorney's Office filed a misdemeanor violation of the Food, Drug and Cosmetic Act. Cephalon has agreed to pay \$50 million to resolve that count.

The settlement resolves allegations that Cephalon promoted drugs Provigil, Gabitril and Actiq for uses other than what the FDA approved. Cephalon also funded continuing medical education program, through millions of dollars in grants, to promote off-label uses for the drugs.

"We hope this case will encourage all drug manufacturers to use prudent, common-sense marketing practices to ensure the safety of our consumers," Attorney General Cooper said.

The drugs allegedly marketed for off-label uses included:

- * Provigil, FDA-approved to treat narcolepsy and sleep disorders. Cephalon marketed the drug as a non-stimulant drug to treat sleepiness, tiredness, decreased activity, lack of energy and fatigue.

- * Gabitril, approved by the FDA as a partial treatment for seizures. Cephalon marketed Gabitril to treat anxiety, insomnia and pain. Following reports of seizures in patients taking Gabitril who did not have epilepsy, the FDA required Cephalon to send a warning to physicians advising them of the risks of seizures in connection with off-label use.

- * Actiq, FDA-approved to treat some cancer patients (those patients for whom morphine-based painkillers are no longer effective). Cephalon marketed Actiq for such conditions as migraines,

sickle-cell pain crises, injuries and in anticipation of changing wound dressing or radiation therapy.

The settlement reimburses the federal and participating states for excessive amounts paid by the Medicaid program as a result of Cephalon's off-label marketing campaign. Cephalon has entered an agreement with the Department of Health and Human Services and Office of the Inspector General, requiring strict scrutiny of its future marketing and sales practices.